

CLAIMS

1. A human growth hormone formulation comprising:
  - a) 1 mg/ml to 20 mg/ml human growth hormone,
  - b) buffer system providing pH 5.5 to pH 7,
  - 5 c) a tonicifying agent, and
  - d) an effective amount of Polyethylene glycol,in a sterile pharmaceutically acceptable liquid.
2. The human growth hormone formulation of claim 1 wherein the polyethylene glycol is PEG 1450 to PEG 20000.
- 10 3. The human growth hormone formulation of claim 2 wherein the polyethylene glycol is 5 mg/mL to 50 mg/mL.
4. The human growth hormone formulation of any one of claims 1 to 3 wherein said formulation is long term cold storage stable for 6 to 18 months at 2°C to 8°C.
- 15 5. The human growth hormone formulation of claim 4 including an antimicrobial agent.
6. The human growth hormone formulation of claim 5 wherein the polyethylene glycol is PEG 1450 to PEG 20000.
7. The human growth hormone formulation of claim 6 wherein the
- 20 polyethylene glycol is 5 mg/mL to 50 mg/mL.
8. The human growth hormone formulation of claim 4 wherein the buffer system provides a pH 6.
9. The human growth hormone formulation of claim 8 wherein the tonicifying agent is mannitol.
- 25 10. The human growth hormone formulation of claim 4 including a chelating agent.
11. The human growth hormone formulation of claim 10 wherein the buffer system provides about pH 6.4.
12. The human growth hormone formulation of claim 11 including an
- 30 antimicrobial agent.
13. A method for using human growth hormone comprising the steps of
  - A) formulating said human growth hormone into an aqueous liquid formulation comprising:

- a) 1 mg/ml to 20 mg/ml human growth hormone,  
b) buffer system providing pH 5.5 to pH 7,  
c) 5 mg/mL to 50 mg/mL polyethylene glycol, and  
d) a tonicifying agent,  
5 in a pharmaceutically acceptable, injectable sterile aqueous vehicle,  
B) storing said formulation as an aqueous liquid for from six to 18  
months at 2°C to 8°C thereby forming a stored formulation; and  
C) directly injecting said stored formulation into a patient in need of  
human growth hormone therapy.
- 10 14. A method for using human growth hormone comprising the steps of  
A) formulating said human growth hormone into an aqueous liquid  
formulation consisting essentially of:  
a) 1 mg/ml to 20 mg/ml human growth hormone,  
b) buffer system providing pH 5.5 to pH 7,  
15 c) 5 mg/mL to 50 mg/mL polyethylene glycol,  
d) 20 to 100 mg/mL of a tonicifying agent and  
e) an antimicrobial agent,  
in a pharmaceutically acceptable, injectable sterile aqueous vehicle,  
B) storing said formulation as an aqueous liquid for from six to 18  
20 months at 2°C to 8°C thereby forming a stored formulation; and  
C) directly injecting said stored formulation into a patient in need of human  
growth hormone therapy.
- 25 15. A method of making a storage stable aqueous formulation of human  
growth hormone comprising mixing said human growth hormone into an aqueous,  
pharmaceutically acceptable vehicle which comprises  
a) 1 mg/ml to 20 mg/ml of said human growth hormone;  
b) buffer providing pH 5.5 to pH 7;  
c) 5 mg/mL to 50 mg/mL polyethylene glycol; and  
d) 20 to 100 mg/mL of a tonicifying agent;  
30 wherein said aqueous, pharmaceutically acceptable vehicle is capable of  
storage for 6 to 18 months at 2 to 8° C.